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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,531	03/15/2004	Samuel Achilefu	MRD / 64CP	2309

7590 07/23/2007

WOOD, HERRON & EVANS, L.L.P.
2700 Carew Tower
441 Vine St.
Cincinnati, OH 45202

EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
07/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,531	ACHILEFU ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/9/07; 7/9/07; & 6/7/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *1-31 and 36-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 March 2004* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/7/04 & 7/22/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENT

1. The Examiner acknowledges the amendment filed 4/9/07 wherein the specification was amended and claim 35 was amended.

Note: Claims 1-44 are pending.

APPLICANT'S INVENTION

2. The instant invention is directed to contrast agents and uses thereof.

APPLICANT'S ELECTION

3. Applicant's election of Group 52 (claims 32-35) in the reply filed on 4/9/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Thus, the restriction is deemed proper and is made FINAL.

4. Applicant's response filed 7/9/07 is acknowledged. In the response, Applicant clarified it was not necessary to elect a single disclosed species.

WITHDRAWN CLAIMS

5. Claims 1-31 and 36-44 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

DOUBLE PATENTING REJECTION

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 32-35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 12, and 13 of U.S. Patent No. 6,706,254. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to dyes in combination with an organic solvent. The claims differ in that the instant invention specifically states that fluorescence is enhanced when a dye is in the presence of a biocompatible organic solvent. However, a skilled practitioner in the art would recognize that both the patent and instant invention contain the same components. Thus, since a compound/composition is inseparable from its properties, the compounds/compositions would inherently enhance fluorescence.

8. Claims 32-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,395,257. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a dye in combination with a carrier (biocompatible solvent). The claims differ in that the instant invention specifically discloses that the dye is used in combination with an organic solvent whereas the patented invention comprises open terminology and allows for the presence of additional agents. Furthermore, a skilled practitioner in the art would recognize that the pharmaceutically acceptable carrier of the patented invention includes biocompatible organic solvents. Also, a skilled practitioner in the art would recognize that if both the

instant invention and that of the patented claims have the same components then both would inherently behave the same, be able to enhance fluorescence.

112 REJECTIONS

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32-35: The term "enhance" in independent claim 32 is a relative term which renders the claim indefinite. The term "enhance" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It should be note that since claims 33-35 depend on independent claim 32 which is ambiguous, the dependent claims are also ambiguous.

Claim 35: A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a

question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 35 recites the broad recitation 'polyglycerol' (line 4), 'sorbitol' (line 3), 'starches' (line 5), 'polyol' 9line 3), and 'polysaccharides' (line 5), and the claim also recites 'hyperbranched polyglycerol' (line 4), 'dianhydosorbital' (line 5), hydrogenated starch hydrolysate' (line 4), 'acetylated polyols' (line 5), and 'polydextrose' (line 5) which is the narrower statement of the range/limitation.

Claim 35: Regarding claim 35, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

102 REJECTIONS

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 32-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Eversole et al (SPIE, 1993, Vol. 1862, pages 209-217).

Eversole et al disclose a study involving microdroplet missing resonance spectroscopy. In addition, Eversole et al disclose fluorescent emission resonances in ethanol droplets (see entire document, especially, page 209, abstract and introduction). In particular, bromo-cresol green dye in combination with rhodamine-6G (R6G) dye and ethanol is disclosed (page 215, 'Discussion', lines 1-3). In Figure 8, the spectra from droplets of three solutions are disclosed. The lower spectrum is an unmixed R6G reference. The upper and middle spectra are fromR6G/BCG solutions which are acidified and neutral, respectively. Thus, both Applicant and Eversole et al disclose methods which have enhanced fluorescence and comprise a dye and compatible organic solvent.

13. Claims 32-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Licha et al (US Patent No. 6,083,485).

Licha et al disclose dyes and methods of using the dyes. The compositions of Licha et al comprise a biological detectable unit (B), a hydrophilic group (W), and a dye (F) (column 4, lines 6-28). Possible dyes useful with the instant invention include, cyanine dyes (columns 4-5, bridging paragraph), squarain dyes (column 6, lines 17-45), styryl dyes (column 6, lines 47-62), and merocyanine dyes (columns 6-7, bridging paragraph). Fluorescence radiation is recorded and an image is generated form the data obtained (column 8, lines 46-61). In the formula Bl-(F-Wm)n (column 9, lines 54-

64) the compounds may be added to a n-octanol/Tris buffer. In Example 2 (column 16), a dye composition is disclosed in combination with an organic solvent (isopropanol). Likewise, in Example 7 (column 17), another dye is disclosed in combination with isopropanol. Thus, since both Applicant and Licha et al disclose dyes in combination with a biocompatible organic solvent (i.e., isopropanol), it would be inherent that in both instances fluorescence is enhanced since based on Applicant's claim any dye that is used in combination with an organic solvent results in enhanced fluorescence. In other words, if both Applicant and the prior art disclose the same components, then since a composition is inseparable from its properties, the properties of Applicant's composition (enhanced fluorescence) would also be exhibited by the prior art's composition.

COMMENTS/NOTES

14. The date of the elected invention is the filing date of the application, not that of either parent application. In particular, the invention of claims 32-35 was first disclosed in the instant application. If Applicant is in disagreement with the Examiner regarding the date, it is respectfully requested that Applicant point to page(s) and line number(s) wherein support for the elected invention is found.

15. Applicant is respectfully requested to correct the spellings of 'cyclodextrine' and 'maltodextrine' by removing the letter 'e' at the end of the terms.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D. L. Jones
Primary Examiner
Art Unit 1618

July 18, 2007